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15 April 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 99N-0240

Per the Federal Register Notice of March 1, 1999 (Volume 64, Number 39) regarding Extralabel Drug Use in Animals, we have the following comments:

1. How will the FDA determine a safe level? What will they use? If data not in the approval information or in general domain, then how will they collect it and who will pay for it? Will they force company to collect the data to establish a safe level? How much data will they demand to be collected?

2. Will this rule apply to old approved drugs or just new approvals?

3. Who pays to have the analytical method developed? To what extent will it have to be validated and how many tissues will it have to be validated for?

4. If multiple approvals of same active, will they force all manufacturers to do the same work because of a different salt? If not, how will they decide who does the work? What will they do to generic approvals? Force the originator to pay?

If it is FDA's plan to demand this data for all existing drug that might be used in food animals, please announce your intentions.

Thank you in advance for taking these comments into consideration. If you have any questions, feel free to contact me at 515-955-4600, Ext. 3826.

Sincerely,

Michael Mlodzik
Senior Manager, Pharmaceutical Regulatory Affairs

MRM/cgn

cc: Dave Hustead, OP

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mrm/letter/fedreg.doc 99N-0240

Nancy Cheal,

Acting Associate Director for Policy, Planning and Evaluation Centers for Disease Control and Prevention (CDC).

[FR Doc. 99-4925 Filed 2-26-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-0240]

Agency Information Collection Activities: Proposed Collection; Comment Request; Extralabel Drug Use in Animals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension for an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements for development of residue detection methodology for human or animal drug(s) prescribed for extra label use in animals, when the agency has determined their is reasonable probability this use may present a risk to public health due to residues exceeding a safe level.

DATES: Submit written comments on the collection of information byApril 30, 1999.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506 (c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Extralabel Drug Use in Animals—21 CFR Part 530 (OMB Control No. 0910-0325— Extension)

Description: The Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA), (Pub. L. 103-396), amended the Federal Food, Drug, and Cosmetic Act to permit licensed veterinarians to prescribe extralabel use in animals of approved human and animal drugs. Regulations implementing provisions of AMDUCA are codified under part 530 (21 CFR part 530). A new provision under these regulations, § 530.22(b), permits FDA to establish a safe level for extralabel use in animals, of an approved human or animal drug when the agency determines there is reasonable probability that this use may present a risk to the public health. The extralabel use in animals of an approved human or animal drug that results in residues exceeding the safe level is considered an unsafe use of a drug. In conjunction with the establishment of a safe level, the new provision permits FDA to request development of an acceptable residue detection method for an analysis of residues above any safe level established under part 530. The sponsor may be willing to provide the methodology in some cases, while in others, FDA, the sponsor, and perhaps a third party, (e.g., a State agency or a professional association), may negotiate a cooperative arrangement to develop the methodology. If no acceptable analytical method is developed, the agency would be permitted to prohibit extralabel use of the drug. The respondents may be sponsors of new animal drug(s), State or Federal government, or individuals.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
530.22(b)	2	1	2	4,160	8,320

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate of the time required for this reporting requirement is based on the agency's communication with industry. The agency recognizes that the time to develop residue detection methodology is highly variable and dependent upon the level of difficulty to a certain extent. Based on this information, FDA estimates that two methods of intermediate difficulty for one to two drugs per year would be developed.

Dated: February 23, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99-4875 Filed 2-26-99; 8:45 am]

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